

**ASSEMBLY BILL**

**No. 221**

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**Introduced by Assembly Member Portantino**

February 4, 2009

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An act to amend Section 120917 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 221, as introduced, Portantino. HIV testing: skin punctures.

Existing law permits the Office of AIDS in the State Department of Public Health to participate in a rapid HIV test research program conducted with the federal Centers for Disease Control and Prevention. Under this program, HIV counselors trained by the Office of AIDS in the State Department of Public Health may perform skin punctures for purposes of withdrawing blood for test purposes, if the HIV counselor meets prescribed requirements. One of these requirements is that the HIV counselor must hold a valid certification as a phlebotomist technician by the State Department of Public Health.

This bill would exempt an HIV counselor who is trained by prescribed personnel and in accordance with training requirements established by the department, and who works under a licensed physician and surgeon, from the requirement that he or she hold a valid certification as a phlebotomist technician.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

1 SECTION 1. The Legislature finds and declares all of the  
2 following:

3 (a) The United States Centers for Disease Control and  
4 Prevention estimates that HIV incidence is 40 percent higher than  
5 previously thought.

6 (b) The Office of AIDS in the State Department of Public Health  
7 estimates that between 30,000 and 40,000 Californians are unaware  
8 that they are HIV-positive and, therefore, are not receiving  
9 appropriate HIV treatment and are possibly jeopardizing their own  
10 health, and that of their sex partners and intravenous drug-using  
11 partners.

12 (c) It is therefore in the interest of the people of the State of  
13 California to take steps to ensure that people have greater access  
14 to HIV testing.

15 SEC. 2. Section 120917 of the Health and Safety Code is  
16 amended to read:

17 120917. (a) The department, through its Office of AIDS and  
18 the authorized agents of the office, may participate in a rapid  
19 human immunodeficiency virus test research program conducted  
20 with the federal Centers for Disease Control and Prevention,  
21 involving innovative HIV testing and counseling programs. Under  
22 the rapid HIV test research program, as authorized by this section,  
23 the department may do the following:

24 (1) Perform and report clinical test results using a rapid HIV  
25 test for diagnosis, prior to test approval by the federal Food and  
26 Drug Administration (FDA). However, test performance and  
27 reporting shall only be done to the extent allowed under that  
28 device's investigational approval by the FDA and pursuant to a  
29 California Health and Human Services Agency Institutional Review  
30 Board-approved research protocol.

31 (2) Use a second independent HIV test to confirm initially  
32 reactive test results to the extent allowed under the investigational  
33 approval by the FDA. All rapid tests shall be confirmed using  
34 technology approved by the federal Food and Drug Administration.  
35 If the results from this confirmatory testing differ from the results  
36 of the rapid test, the subject shall be notified. No subject shall  
37 participate in the research protocol who does not provide  
38 appropriate contact information.

(b) An HIV counselor who is trained by the Office of AIDS and working in an HIV counseling and testing site funded by the department through a local health jurisdiction, or its agents, may do all of the following:

(1) Perform any HIV test that is classified as waived under the federal Clinical Laboratory Improvement Act (CLIA) (42 U.S.C. Sec. 263a and following) if all of the following conditions exist:

(A) The performance of the HIV test meets the requirements of CLIA and, *subject to subparagraph (B)*, Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code.

*(B) Notwithstanding Section 1246 of the Business and Professions Code, an HIV counselor may perform skin punctures for the purpose of withdrawing blood for HIV testing, upon specific authorization from a licensed physician and surgeon, provided that the person meets both of the following requirements:*

*(i) He or she works under the direction of a licensed physician and surgeon.*

*(ii) He or she has been trained in accordance with training requirements established by the department, by a licensed physician and surgeon, or by a licensed clinical laboratory scientist or bioanalyst in the proper procedures to be employed when conducting the skin puncture, and has a statement signed by the instructing physician and surgeon, scientist, or bioanalyst that the training has been successfully completed.*

~~(B)~~

(C) The person performing the HIV test meets the requirements for the performance of waived laboratory testing pursuant to subdivision (a) of Section 1206.5 of the Business and Professions Code. For purposes of this subdivision and subdivision (a) of Section 1206.5 of the Business and Professions Code, an HIV counselor trained by the Office of AIDS shall be “other health care personnel providing direct patient care” as referred to in paragraph (12) of subdivision (a) of Section 1206.5 of the Business and Professions Code.

~~(C)~~

(D) The patient is informed that the preliminary result of the test is indicative of the likelihood of HIV infection and that the result must be confirmed by an additional more specific test, or, if approved by the federal Food and Drug Administration for that

1 purpose, a second different rapid HIV test. Nothing in this  
2 subdivision shall be construed to allow an HIV counselor trained  
3 by the Office of AIDS to perform any HIV test that is not classified  
4 as waived under the CLIA.

5 (2) Notwithstanding Sections 1246.5 and 2053 of the Business  
6 and Professions Code, order and report HIV test results from tests  
7 performed pursuant to paragraph (1) to patients without  
8 authorization from a licensed health care professional or his or her  
9 authorized representative. Patients with indeterminate or positive  
10 test results from tests performed pursuant to paragraph (1) shall  
11 be referred to a licensed health care provider whose scope of  
12 practice includes the authority to refer patients for laboratory  
13 testing for further evaluation.

14 (c) Notwithstanding any other provision of law, an HIV  
15 counselor acting in accordance with this section who successfully  
16 completes the HIV counselor training shall be deemed to have  
17 demonstrated sufficient literacy and comprehension to advance to  
18 the limited phlebotomy technician training and may substitute  
19 successful completion of the HIV counselor curriculum for the  
20 requirement for a high school diploma or General Education  
21 Development (GED) equivalent for a limited phlebotomy  
22 technician, as defined in Section 1029.116 of Title 17 of the  
23 California Code of Regulations pursuant to Section 1246 of the  
24 Business and Professions Code.

25 (d) An HIV counselor who meets the requirements of this section  
26 with respect to performing any HIV test that is classified as waived  
27 under the CLIA may not perform any other test unless that person  
28 meets the statutory and regulatory requirements for performing  
29 that other test.